

AMENDMENT TO COMMITTEE PRINT
OFFERED BY MR. STUPAK OF MICHIGAN

[(ped-Exclusiv__003; June 19, 2007)]

Add at the end the following new subsection:

1 (h) PEDIATRIC LABELING.—Section 505A of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a),
3 as amended by subsection (a)(1), is amended by adding
4 at the end the following:

5 “(r) LABELING CHANGE AS CONDITION OF MARKET
6 EXCLUSIVITY.—Notwithstanding any other provision of
7 this section, the Secretary may not, pursuant to a study
8 under subsection (b) or (c), extend any period of market
9 exclusivity referred to in such subsection until the labeling
10 of the drug involved bears an appropriate statement of
11 whether and to what extent the findings of the study pro-
12 vide information on the safety and effectiveness of the
13 drug when used in children, except that such limitation
14 on extending market exclusivity for the drug does not
15 apply if the total remaining period of such exclusivity is
16 three years or less. Nothing in this subsection shall be con-
17 strued as preventing the Secretary from requesting addi-
18 tional information from a manufacturer under subsections
19 (b) and (c).”.